Docket No.: HO-P02540US1
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:
Gordon S. Scholler

Application No.: 09/896,429 Art Unit: 3739

Filed: June 29, 2001 Examiner: A. Farah

For: IMPROVED APPLANATION LENS AND METHOD FOR OPHTHALMIC SURGICAL APPLICATIONS

## DECLARATION UNDER 37 CFR §1.132

Dear Sir:

I, Gordon S. Scholler, on personal knowledge do hereby state as follows:

1. I am a United States citizen residing at 16418 Bronco Lane, Poway, CA 92064. I am employed by the applicant, IntraLase Corp.

2. IntraLase is licensed under U.S. Pat. No. 5,549,632 (the "Lai '632 patent"), which describes a laser system and applanator plate that can be used in ophthalmic surgery.

3. IntraLase manufactures and sells to ophthalmic surgeons a laser system that is used to form a flap in corneal tissue for the first step in the procedure known as *laser in situ keratomileusis* (LASIK). The surgeon creates the flap using laser energy in a precisely controlled way to photodisrupt tissue below the surface of the cornea. The flap is held by an instrument and lifted to expose underlying internal corneal tissue to be shaped by another laser. Afterward, the flap is returned to its original position. This procedure changes the refractive characteristics of the eye to improve the patient's vision.

4. One component for success of this operation is a patient interface device, which stabilizes the patient's eye and holds the laser system in a fixed position relative to the patient's eye. The patient interface holds the laser system in place relative to the eye so that the laser can form the flap at precisely the right location and depth. When coupled to the

laser system, a critical part of the patient interface is an applanation lens that contacts the eye.

5. The applanation lens must be biocompatible because it contacts the eye, and cannot be formed of a material or create by-products of a material that could irritate or damage the sensitive corneal tissue. The lens must also be sterilized, preferably with gamma radiation. Gamma radiation is preferred to other acceptable methods of sterilization because it lends itself to process controls that result in reduced within-process variability thereby producing higher repeatability from one sterilization run to another. Also, compared with other methods, sterilization by gamma radiation leaves no undesirable residue and is more cost effective. The lens must also be formed of a transparent material, have a high level of transmittance for light in the ranges used by lasers, from UV to IR. The lens material must also be able to transmit the laser light without melting or sputtering to create by-products that would injure eye tissue.

6. I, and my team, began testing plastics of the type described in the Lai '632 patent, which had previously been used in other types of eye products. The Lai '632 patent, col. 7, lns. 47-49, describes that "[t]he applanator plate 111 is preferably constructed of a transparent light weight plastic, such as acrylic." After testing a number of plastic materials, we found that none of them was satisfactory because they either melted or sputtered when laser energy was transmitted through the lens. This effect was unacceptable because the sputtered or melted plastic could injure the eye or cause scarring.

7. We next decided to test an optical boron glass material that appeared to be promising because it was biocompatible, had a high degree of transmittance, and would not melt or sputter too much when subjected to laser energy. This material worked well in initial tests. However, when it was sterilized by exposure to gamma radiation it unexpectedly discolored and lost about 20% of its ability to transmit light at the wavelength used in our laser system.

8. Then we looked for a biocompatible material that would not sputter unacceptably or melt, one that had a high degree of transmittance for laser light, and, when exposed to gamma radiation, would not lose transmittance at the wavelength at which our laser operates. The team looked at various types of silica and found that crystalline forms of silica like those used in making glass would also discolor and lose transmittance, but that an

amorphous, noncrystalline, synthetic silicon dioxide, called synthetic fused silica, would not discolor when exposed to gamma radiation. This material was tried and found to work. It did not discolor or result in a lower transmittance after being sterilized with gamma radiation.

9. I hereby declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: February 12, 2004

Gordon S. Scholler